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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 710, 738, 740, 745, 772 and 774

[Docket No. 131211999-3999-01]

RIN 0694-AG04

Implementation of the Understandings Reached at the June 2013 Australia Group (AG)

Plenary Meeting and the December 2012 AG Intersessional Decisions

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Industry and Security (BIS) publishes this final rule to amend the Export Administration Regulations (EAR) to implement the understandings reached at the June 2013 plenary meeting of the Australia Group (AG) and the December 2012 AG intersessional decisions. Specifically, this rule amends the Commerce Control List (CCL) entry

in the EAR that controls equipment capable of handling biological materials to reflect the 2013 AG Plenary understanding that clarifies controls on fermenters, and certain components thereof, in the AG “Control List of Dual-Use Biological Equipment and Related Technology and Software.” This rule also amends the CCL entry that controls certain animal pathogens to reflect a recommendation made at the 2013 AG Plenary meeting, which was later adopted pursuant to the AG silent approval procedure, to revise the AG “List of Animal Pathogens for Export Control” to clarify the controls on the Lyssavirus genus. In addition, this rule amends the EAR to reflect the addition of Mexico as a participating country in the AG following the 2013 AG Plenary meeting.

The recommendations agreed to through the silent approval procedure included changes to the controls on *Clostridium perfringens* in the AG “List of Biological Agents for Export Control” and changes to the description of “genetic elements,” which are included in three of the AG common control lists. This rule also amends the CCL entry that controls chemical manufacturing facilities and equipment to reflect the AG intersessional decision to clarify the controls that apply to certain agitators for use in reaction vessels or reactors described in the CCL entry and to impellers, blades or shafts designed for such agitators.

This rule also adds a License Exception STA paragraph to the CCL entry that controls human and zoonotic pathogens and toxins to clarify the scope of eligible items. Finally, this rule amends the EAR to reflect the addition of Somalia and Syria as States Parties to the Chemical Weapons Convention (CWC).

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Comments on the information collection may be submitted at any time.

ADDRESSES: Send comments regarding this collection of information, including suggestions for reducing the burden, to Jasmeet Seehra, Office of Management and Budget (OMB), by e-mail to Jasmeet_K._Seehra@omb.eop.gov, or by fax to (202) 395-7285; and to the Regulatory Policy Division, Bureau of Industry and Security, Department of Commerce, 14th Street & Pennsylvania Avenue, N.W., Room 2705, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Elizabeth Sangine, Director, Chemical and Biological Controls Division, Office of Nonproliferation and Treaty Compliance, Bureau of Industry and Security, Telephone: (202) 482-3343.

SUPPLEMENTARY INFORMATION:

Background

The Bureau of Industry and Security (BIS) is amending the Export Administration Regulations (EAR) to implement the understandings reached at the Australia Group (AG) plenary meeting held in Paris, France, on June 3-7, 2013. This rule also implements the recommendations presented at the AG intersessional implementation meeting held in Bonn, Germany, on

December 6-7, 2012, and adopted pursuant to the AG silent approval procedure, which closed on March 11, 2013. The AG is a multilateral forum consisting of 41 participating countries that maintain export controls on a list of chemicals, biological agents, and related equipment and technology that could be used in a chemical or biological weapons program. The AG periodically reviews items on its control list to enhance the effectiveness of participating governments' national controls and to achieve greater harmonization among these controls.

June 2013 AG Plenary Changes.

The June 2013 AG plenary meeting adopted understandings that affected the AG "Control List of Dual-Use Biological Equipment and Related Technology and Software." This rule amends Export Control Classification Number (ECCN) 2B352 to reflect the AG plenary changes to this AG common control list. Specifically, ECCN 2B352 (Equipment capable of use in handling biological materials) is amended by revising 2B352.b to indicate that this ECCN controls fermenters with a capacity of 20 liters or greater that are capable of the cultivation of pathogenic micro-organisms, or of live cells, for the production of pathogenic viruses or toxins without the propagation of aerosols. These fermenters are described in new subparagraph b.1 of ECCN 2B352.b.

This rule also amends ECCN 2B352.b to indicate that this ECCN controls the following components designed for the fermenters described above: cultivation chambers designed to be sterilized or disinfected in situ; cultivation chamber holding devices; and process control units

capable of simultaneously monitoring and controlling two or more fermentation system parameters (e.g. temperature, pH, nutrients, agitation, dissolved oxygen, air flow, foam control).

These components are described in new subparagraph b.2 of ECCN 2B352.b.

In addition, this rule amends the Technical Note to ECCN 2B352.b to clarify that the “fermenters” controlled under this ECCN include all types of bioreactors, including “single-use (disposable) bioreactors,” as well as chemostats and continuous-flow systems.

There was also a recommendation made at the 2013 AG Plenary meeting to revise the AG “List of Animal Pathogens for Export Control” to clarify the controls on Lyssavirus (a.k.a. Rabies).

This recommendation was adopted pursuant to the AG silent approval procedure, which closed on July 14, 2013. Consistent with this AG change, this rule amends ECCN 1C352 a.8 to clarify that it controls the Rabies virus and all other members of the Lyssavirus genus.

December 2012 AG Intersessional Changes.

This rule also implements the recommendations presented at the AG intersessional implementation meeting held in December 2012 and adopted pursuant to the AG silent approval procedure in March 2013. These recommendations included changes to the AG “List of Biological Agents for Export Control” and to the description of “genetic elements,” as the term is used in this AG list, as well as in the AG “List of Animal Pathogens for Export Control” and the AG “List of Plant Pathogens for Export Control.”

This rule amends ECCN 1C351 (Human and zoonotic pathogens and toxins) to reflect the AG intersessional changes to the AG “List of Biological Agents for Export Control.” Specifically, ECCN 1C351.d.5 is revised to clarify that the export controls on *Clostridium perfringens* apply only to the following exotoxins: *Clostridium perfringens* alpha, beta 1, beta 2, epsilon and iota toxins. Prior to this change, ECCN 1C351.d.5 referred to *Clostridium perfringens* toxins, generally.

In addition, this rule amends ECCN 1C353 to reflect the AG intersessional changes to the description of “genetic elements” in the AG common control lists for biological agents, animal pathogens, and plant pathogens. Specifically, this rule revises the Technical Note 1 to ECCN 1C353 to clarify that “genetic elements” include, inter alia, not only chromosomes, genomes, plasmids, transposons, and vectors, whether genetically modified or unmodified, but also those chromosomes, genomes, plasmids, transposons, and vectors that have been “chemically synthesized in whole or in part.”

This rule also amends the introductory text of ECCN 2B350.b, which controls agitators for use in reaction vessels or reactors described in 2B350.a and impellers, blades or shafts designed for such agitators. Specifically, the introductory text of ECCN 2B350.b is revised to read as follows: “Agitators designed for use in reaction vessels or reactors described in 2B350.a, and impellers, blades or shafts designed for such agitators, where all surfaces that come in direct contact with the chemical(s) being processed or contained are made from any of the following materials.” This change is intended to clarify that ECCN 2B350.b controls only agitators (and

impellers, blades or shafts for such agitators) where: (1) the agitators are for use in reaction vessels or reactors described in 2B350.a; and (2) all surfaces of the agitators (and of the impellers, blades or shafts for such agitators) that come in direct contact with the chemical(s) being processed or contained are made from any of the materials identified in ECCN 2B350.b.1 through .b.8.

Change in frequency of “sample shipment” reports required under ECCN 1C350.

This rule amends the “sample shipments” provisions in License Requirement Note 1 of ECCN 1C350 to change the reporting requirement from quarterly to annual, consistent with the frequency of the reports required for imports and exports of CWC Schedule 2 and 3 chemicals under Sections 713.3 and 714.2, respectively, of the Chemical Weapons Convention Regulations (CWCR) (15 CFR parts 710-721). Consistent with the CWCR timetable, annual reports of “sample shipments” under ECCN 1C350 must be submitted to BIS no later than February 28 of the year following the calendar year in which the “sample shipments” were made.

Addition of Mexico as a Participating Country in the AG.

This final rule amends the EAR to reflect the addition, on August 12, 2013, of Mexico as a participating country in the Australia Group (AG). Specifically, this rule amends Supplement No. 1 to part 738 of the EAR (Commerce Country Chart) by revising the entry for Mexico to remove the license requirements indicated under CB Column 2. This rule also amends

Supplement No. 1 to part 740 of the EAR (Country Groups) by adding Mexico to Country Group A:3 (Australia Group). In addition, this rule revises the definition of “Australia Group” in Section 772.1 of the EAR (Definitions of Terms used in the EAR) by adding Mexico.

Addition of Somalia and Syria as States Parties to the Chemical Weapons Convention (CWC).

This rule also amends the EAR to reflect the addition of Somalia and Syria as States Parties to the CWC on June 28, 2013, and October 14, 2013, respectively. Specifically, this rule amends Supplement No. 2 to part 745 of the EAR (States Parties to the CWC) to add Somalia and Syria in alphabetical order. Because Somalia is not an AG participating country, its addition to the list of CWC States Parties in Supplement No. 2 to part 745 does not affect the CB Column 1 and CB Column 2 license requirements for Somalia that are indicated in Supplement No. 1 to part 738 of the EAR (Commerce Country Chart). However, a license is no longer required for CB or CW (chemical weapons) reasons for exports to Somalia of mixtures and test kits controlled under ECCN 1C395.a and .b, respectively, although a license would be required if any of the end-user or end-use requirements in part 744 of the EAR apply. The addition of Syria to the list of CWC States Parties in Supplement No. 2 to part 745 does not affect any CB or CW license requirements for exports to Syria, because Section 746.9(a) of the EAR requires a license for exports and reexports to Syria of all items subject to the EAR (including, but not limited to, all items identified on the CCL), except for food and medicine classified as EAR99.

In order to maintain consistency between the EAR and the Chemical Weapons Convention Regulations (CWCR) (15 CFR parts 710-721), with respect to those countries that are identified

as States Parties to the CWC, this rule also amends Supplement No. 1 to part 710 of the CWC (States Parties to the CWC) to add the following countries in alphabetical order: Bahamas, Barbados, Congo (Democratic Republic of the), Dominican Republic, Iraq, Somalia, and Syria.

License Exception STA paragraph added to ECCN 1C351.

In addition to the changes related to the AG or the CWC described above, this final rule also adds a License Exception STA paragraph to the license exceptions section of ECCN 1C351 in order to clarify the existing eligibility requirements for certain items controlled under this ECCN. Specifically, the new License Exception STA paragraph in ECCN 1C351 indicates that paragraph (c)(1) of License Exception STA (see Section 740.20(c)(1) of the EAR) may be used for items in 1C351.d.1 through 1C351.d.10 and 1C351.d.13 through 1C351.d.19. Exporters are referred to Section 740.20(b)(2)(vi) of the EAR for restrictions on the quantity of any one toxin that may be exported in a single STA shipment and the number of STA shipments that may be made to any one end user in a single calendar year. This STA paragraph also reminds exporters about the Automated Export System (AES) requirements in Section 758.1(b)(4) of the EAR, which apply to all STA shipments.

Effect of this rule on the scope of the CB controls in the EAR.

The changes made by this rule only marginally affect the scope of the EAR controls on biological agents and toxins, chemical manufacturing facilities/equipment, and equipment

capable of use in handling biological materials. Specifically, the amendments to the List of Items Controlled in ECCNs 1C351 (human and zoonotic pathogens) and 2B352 (biological equipment) and to Technical Note 1 to ECCN 1C353 (genetic elements) do not affect the scope of the controls in these ECCNs to a degree that would significantly impact the number of license applications that would have to be submitted for the affected items controlled therein.

As indicated above, the addition of Somalia and Syria to the list of CWC States Parties in Supplement No. 2 to part 745 of the EAR is expected to have very little impact on the number of license applications that will have to be submitted for these destinations. Similarly, the addition of a License Exception STA paragraph to ECCN 1C351 and the clarifications to the controls on agitators in ECCN 2B350.b do not alter the scope of the controls that apply to any of the affected items in these ECCNs.

However, the amendments to the EAR to reflect the addition of Mexico as a participating member of the AG are expected to result in a modest reduction in the number of license applications that will have to be submitted for exports of precursor chemicals (ECCN 1C350) and chemical/biological production and processing equipment (ECCNs 2B350, 2B351, and 2B352). These items generally will no longer require a license to Mexico because, in response to the addition of Mexico as a participating member of the AG, this rule removes the license requirements indicated for Mexico under CB Column 2 of the Commerce Country Chart.

Although the Export Administration Act expired on August 20, 2001, the President, through

Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013), and as extended by the Notice of August 8, 2013, 78 FR 49107 (August 12, 2013), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act. BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a “significant regulatory action” although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) (PRA), unless that collection of information displays a currently valid Office of

Management and Budget (OMB) Control Number. This rule contains a collection of information subject to the requirements of the PRA. This collection has been approved by OMB under Control Number 0694-0088 (Multi-Purpose Application), which carries a burden hour estimate of 58 minutes to prepare and submit form BIS-748. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Jasmeet Seehra, Office of Management and Budget (OMB), and to the Regulatory Policy Division, Bureau of Industry and Security, Department of Commerce, as indicated in the “ADDRESSES” section of this rule.

3. This rule does not contain policies with Federalism implications as that term is defined in Executive Order 13132.

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military and foreign affairs function of the United States (See 5 U.S.C. 553(a)(1)). Immediate implementation of these amendments is non-discretionary and fulfills the United States’ international obligation to the Australia Group (AG). The AG contributes to international security and regional stability through the harmonization of export controls and seeks to ensure that exports do not contribute to the development of chemical and biological weapons. The AG consists of 41 member countries that act on a consensus basis and the amendments set forth in this rule implement the understandings reached at the June 2013 AG plenary meeting, the December 2012 AG intersessional changes,

and other changes that are necessary to ensure consistency with the controls maintained by the AG. Since the United States is a significant exporter of the items in this rule, immediate implementation of this provision is necessary for the AG to achieve its purpose. Any delay in implementation will create a disruption in the movement of affected items globally because of disharmony between export control measures implemented by AG members, resulting in tension between member countries. Export controls work best when all countries implement the same export controls in a timely and coordinated manner.

Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this final rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under the Administrative Procedure Act or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) are not applicable. Therefore, this regulation is issued in final form.

List of Subjects

15 CFR Part 710

Chemicals, Exports, Foreign Trade, Imports, Treaties.

15 CFR Part 738

Administrative practice and procedure, Exports, Foreign trade

15 CFR Part 740

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements

15 CFR Part 745

Administrative practice and procedure, Chemicals, Exports, Foreign trade, Reporting and recordkeeping requirements

15 CFR Part 772

Exports

15 CFR Part 774

Exports, Reporting and recordkeeping requirements

For the reasons stated in the preamble, part 710 of the Chemical Weapons Convention

Regulations (15 CFR parts 710-721) and parts 738, 740, 745, 772 and 774 of the Export Administration Regulations (15 CFR parts 730-774) are amended as follows:

PART 710 – [AMENDED]

1. The authority citation for 15 CFR Part 710 continues to read as follows:

Authority: 22 U.S.C. 6701 *et seq.*; E.O. 13128, 64 FR 36703, 3 CFR 1999 Comp., p. 199.

2. Supplement No. 1 to Part 710 is amended by revising the undesignated center heading “List of States Parties as of December 20, 2008” to read “List of States Parties as of November 1, 2013” and by adding, in alphabetical order, the countries “Bahamas”, “Barbados”, “Congo (Democratic Republic of the)”, “Dominican Republic”, “Iraq”, “Somalia”, and “Syria”.

PART 738 – [AMENDED]

3. The authority citation for 15 CFR Part 738 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c; 22 U.S.C. 3201 *et seq.*; 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 15 U.S.C. 1824a; 50 U.S.C. app. 5;

22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

4. Supplement No. 1 to Part 738 is amended by revising the entry for “Mexico” to read as follows:

Supplement No. 1 to Part 738--COMMERCE COUNTRY CHART

[Reason for control]

Countries	Chemical and biological weapons			Nuclear nonproliferation		National security		Missile tech	Regional stability		Firearms convention	Crime control			Anti-terrorism	
	CB 1	CB 2	CB 3	NP 1	NP 2	NS 1	NS 2	MT 1	RS 1	RS 2	FC 1	CC 1	CC 2	CC 3	AT 1	AT 2
						*	*	*	*	*						
Mexico	X			X		X	X	X	X	X	X	X		X		
						*	*	*	*	*						

- Authority:* 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 7201 *et seq.*;
E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001
Comp., p. 783; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

- ### Country Group A

Country	[A:1]	[A:2] Missile technology control regime	[A:3] Australia group	[A:4] Nuclear suppliers group	[A:5]	[A:6]
* * * * *						
Mexico			X			
* * * * *						

PART 745 – [AMENDED]

7. The authority citation for 15 CFR Part 745 continues to read as follows:

Authority: 50 U.S.C. 1701 *et seq.*; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; Notice of November 7, 2013, 78 FR 67289 (November 12, 2013).

8. Supplement No. 2 to Part 745 is amended by revising the undesignated center heading “List of States Parties as of May 21, 2009” to read “List of States Parties as of November 1, 2013” and by adding, in alphabetical order, the countries “Somalia” and “Syria”.

PART 772 – [AMENDED]

9. The authority citation for 15 CFR Part 772 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

10. In § 772.1, the definition of “Australia Group” is revised to read as follows:

§ 772.1 Definitions of terms as used in the Export Administration Regulations (EAR).

* * * * *

Australia Group. The countries participating in the Australia Group have agreed to adopt harmonized controls on certain dual-use chemicals (i.e., precursor chemicals), biological agents, related manufacturing facilities and equipment, and related technology in order to ensure that exports of these items do not contribute to the proliferation of chemical or biological weapons. Countries participating in the Australia Group as of November 1, 2013, include: Argentina, Australia, Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Korea (South), Latvia, Lithuania, Luxembourg, Malta, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, the United Kingdom, and the United States. See also §742.2 of the EAR.

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PART 774 - [AMENDED]

11. The authority citation for 15 CFR Part 774 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.*; 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 15 U.S.C. 1824a; 50 U.S.C. app. 5; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

12. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1-- Special Materials and Related Equipment, Chemicals, “Microorganisms” and “Toxins,” ECCN 1C350 is amended, under the License Requirements section, by revising paragraph .e of License Requirement Note 1 (“Sample Shipments”) to read as follows:

Supplement No. 1 to Part 774 – The Commerce Control List

* * * * *

1C350 Chemicals that may be used as precursors for toxic chemical agents.

License Requirements

* * * * *

License Requirement Notes**1. *Sample Shipments:*** * * *

* * * * *

e. Annual report requirement. The exporter is required to submit an annual written report for shipments of samples made under this Note 1. The report must be on company letterhead stationery (titled “Report of Sample Shipments of Chemical Precursors” at the top of the first page) and identify the chemical(s), Chemical Abstract Service Registry (C.A.S.) number(s), quantity(ies), the ultimate consignee's name and address, and the date of export for all sample shipments that were made during the previous calendar year. The report must be submitted no later than February 28 of the year following the calendar year in which the sample shipments were made, to: U.S. Department of Commerce, Bureau of Industry and Security, 14th Street and Pennsylvania Ave., NW., Room 2099B, Washington, DC 20230, Attn: “Report of Sample Shipments of Chemical Precursors.”

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13. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1--
Special Materials and Related Equipment, Chemicals, “Microorganisms” and “Toxins,” ECCN
1C351 is amended, under the List Based License Exceptions section, by adding an “STA”
paragraph following the “CIV” paragraph and, under the List of Items Controlled section, by
revising paragraph d.5 in the “Items” paragraph to read as follows:

1C351 Human and zoonotic pathogens and “toxins”, as follows (see List of Items Controlled).

* * * * *

List Based License Exceptions (See Part 740 for a description of all license exceptions)

LVS: * * *

GBS: * * *

CIV: * * *

Special Conditions for STA

STA: (1) Paragraph (c)(1) of License Exception STA (§ 740.20(c)(1)) may be used for items in 1C351.d.1 through 1C351.d.10 and 1C351.d.13 through 1C351.d.19. See § 740.20(b)(2)(vi) for restrictions on the quantity of any one toxin that may be exported in a single shipment and the number of shipments that may be made to any one end user in a single calendar year. Also see the Automated Export System (AES) requirements in § 758.1(b)(4) of the EAR. (2) Paragraph (c)(2) of License Exception STA (§ 740.20(c)(2) of the EAR) may not be used for any items in 1C351.

List of Items Controlled

Related Controls: * * *

Related Definitions: * * *

Items:

* * * * *

d. * * *

d.5. *Clostridium perfringens* alpha, beta 1, beta 2, epsilon and iota toxins;

* * * * *

14. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1--Special

Materials and Related Equipment, Chemicals, “Microorganisms” and “Toxins,” ECCN 1C352 is amended by revising paragraph a.8. in the “Items” paragraph under the List of Items Controlled section to read as follows:

1C352 Animal pathogens, as follows (see List of Items Controlled).

* * * * *

List of Items Controlled

Related Controls: * * *

Related Definitions: * * *

Items:

a. * * *

a.8. Rabies virus and all other members of the Lyssavirus genus;

* * * * *

15. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1--Special

Materials and Related Equipment, Chemicals, “Microorganisms” and “Toxins,” ECCN 1C353 is amended by revising Technical Note 1, following the “Items” paragraph under the List of Items Controlled section, to read as follows:

1C353 Genetic elements and genetically modified organisms, as follows (see List of Items Controlled).

* * * * *

List of Items Controlled

Related Controls: * * *

Related Definition: * * *

Items:

* * * * *

Technical Notes:

1. “Genetic elements” include, inter alia, chromosomes, genomes, plasmids, transposons,

and vectors, whether genetically modified or unmodified, or chemically synthesized in whole or in part.

* * * * *

16. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 2 -- Materials Processing, ECCN 2B350 is amended by revising the introductory text of paragraph b. in the “Items” paragraph under the List of Items Controlled section to read as follows:

2B350 Chemical manufacturing facilities and equipment, except valves controlled by 2A226 or 2A292, as follows (see List of Items Controlled).

* * * * *

List of Items Controlled

Related Controls: * * *

Related Definition: * * *

Items:

a. * * *

b. Agitators designed for use in reaction vessels or reactors described in 2B350.a, and impellers,

blades or shafts designed for such agitators, where all surfaces that come in direct contact with the chemical(s) being processed or contained are made from any of the following materials:

* * * * *

17. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 2 -- Materials Processing, ECCN 2B352 is amended under the “Items” paragraph in the List of Items Controlled section by revising paragraph b. and the Technical Note thereto to read as follows:

2B352 Equipment capable of use in handling biological materials, as follows (see List of Items Controlled).

* * * * *

List of Items Controlled

Related Controls: * * *

Related Definitions: * * *

Items:

a. * * *

b. Fermenters and components as follows:

b.1. Fermenters capable of cultivation of pathogenic micro-organisms or of live cells for the production of pathogenic viruses or toxins, without the propagation of aerosols, having a capacity of 20 liters or greater.

b.2. Components designed for such fermenters, as follows:

b.2.a. Cultivation chambers designed to be sterilized or disinfected in situ;

b.2.b. Cultivation chamber holding devices; or

b.2.c. Process control units capable of simultaneously monitoring and controlling two or more fermentation system parameters (e.g., temperature, pH, nutrients, agitation, dissolved oxygen, air flow, foam control).

Technical Note: Fermenters include bioreactors (including single-use (disposable) bioreactors), chemostats and continuous-flow systems.

* * * * *

DATED: March 18, 2014

Kevin J. Wolf

Assistant Secretary

for Export Administration

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